AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

Serial Number: 09/060047 Filing Date: April 14, 1998

Title: EMULSIONS FOR IN-SITU DELIVERY SYSTEM

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IN THE CLAIMS

Please amend the claims as follows.

- 1. (Currently Amended) A composition for delivering a biologically active agent, comprising: a low viscosity an emulsion of a biologically active mixture and a controlled release formulation, the biologically active mixture emprising consisting essentially of the biologically active agent and a pharmaceutically acceptable, aqueous medium as a protective carrier; and the controlled release formulation comprising a pharmaceutically acceptable, biodegradable thermoplastic polymer that is substantially insoluble in an aqueous or body fluid and a pharmaceutically acceptable organic solvent having a water solubility of from about 2 percent to about 20 percent by weight relative to a weight of a combination of organic solvent and water, and wherein the concentration of polymer in organic solvent ranges from about 0.5 gm per ml to about 3 gm per ml and the composition is used to form an *in situ* solid implant.
- 2. (Previously Presented) A precomposition suitable for preparing a composition according to claim 1, comprising separate containers of the biologically active mixture and controlled release formulation, which containers are adapted to cause combination of the biologically active mixture and controlled release formulation.
- 3. (Previously Presented) A composition of claim 1, wherein the biologically active agent is selected from the group consisting of an antiinflammatory agent, an antibacterial agent, an antifungal agent, an analgesic agent, an anesthetic agent, an immunogen, a vaccine, an antineoplastic agent, a growth or survival agent, a hormone, a cardiovascular agent, an anti-ulcer agent, a bronchial agent, a central nervous system agent, a gene, a gene fragment, an insertion vector carrying a gene or gene fragment, and any combination or multiple thereof.

Claims 4-13 (Canceled).

14. (Previously Presented) A composition of claim 1 wherein the thermoplastic polymer formula contains monomeric units selected from the group consisting of lactide, glycolide,

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caprolactone, anhydride, amide, urethane, esteramide, orthoester, dioxanone, acetal, ketal

carbonate, phosphazene, hydroxybutyrate, hydroxyvalerate, alkylene oxalate, alkylene succinate,

amino acid and any copolymer and terpolymer combination of these monomeric units in random

order or in block order.

15. (Previously Presented) A composition of claim 14 wherein the monomeric units include

lactide, glycolide, caprolactone, hydroxybutyrate, and any combination thereof.

Claims 16-18 (Canceled)

19. (Previously Presented) A composition of claim 1, wherein the emulsion is a water-in-oil

emulsion.

Claims 20-27 (Canceled).

28. (Previously Presented) A composition of claim 1 wherein the thermoplastic polymer is in

mixture with a non-polymeric material.

29. (Currently Amended) A composition of claim 1 wherein the aqueous carrier has a water-

like consistency and is water, saline, physiological buffer solution, cell-culture medium, aqueous

nutrient medium, aqueous mineral medium, aqueous amino acid medium, aqueous lipid medium,

aqueous vitamin medium or any combination thereof.

30. (Previously Presented) A composition of claim 1 wherein the organic solvent is selected

from the group consisting of esters of carbonic acid and alkyl alcohols, alkyl esters of mono-, di-,

and tricarboxylic acids, and alkyl ketones.

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31. (Previously Presented) A composition of claim 1 wherein the organic solvent is selected from the group consisting of propylene carbonate, diethyl malonate, ethylene carbonate, dimethyl carbonate, 2-ethoxy ethyl acetate, ethyl acetate, methyl acetate, ethyl butyrate, diethyl glutonate, tributyl citrate, diethyl succinate, tributyrin, isopropyl myristate, dimethyl adipate, dimethyl succinate, dimethyl oxalate, dimethyl citrate, triethyl citrate, acetyl tributyl citrate, glyceryl triacetate, methyl ethyl ketone.

32. (New) A composition of claim 1 wherein the aqueous medium includes a component selected from the group consisting of an emulsifying agent, a surfactant, an excipient, a colorant and any combination thereof.